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OCT 4 - 2005

510(k) Summary

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Patricia Sandborn Beres
Senior Regulatory Specialist

Proprietary Name(s): Ranawat Burstein® Acetabular Components, Full Hemisphere Acetabular Components, Quadrant Sparing Shells, and McLaughlin™ +5 Acetabular System.

Common or Usual Name: Acetabular component for a total hip replacement

Classification Name:
1) Hip joint metal/polymer constrained cemented or uncemented prosthesis (21 CFR 888.3310)
2) Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis (21 CFR 888.3330)
3) Hip joint metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3350)
4) Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21 CFR 888.3353)
5) Hip joint metal/polmer/metal semi-constrained, porous-coated, uncemented prosthesis (21 C.F.R. 888.3358)

Device Product Code: KWZ, KWA, JDI, MAY, MEH, LPH

Legally Marketed Devices To Which Substantial Equivalence Is Claimed: The devices contained in this 510(k) submission are substantially equivalent to devices cleared through the following 510(k)s:

Ranawat Burstein® Total Hip System	K921277
Full Hemisphere Ring-Loc Liner	K920640
Expanded Indications for Non-cemented Porous Coated Hips	K030055

Device Description: All devices are metallic, full-hemisphere, acetabular shell components. Each shell utilizes a modular polyethylene liner and a femoral head component that is taper fit onto a femoral stem at the time of surgery.

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Porous Coated Acetabular Components
Page 2

Intended Use: Cemented or non-cemented total hip replacement in case of

1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
2) Rheumatoid arthritis
3) Correction of functional deformity
4) Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques.
5) Revision procedures where other treatment or devices have failed.

M2a™ Ring-Loc liners are only cleared for use in non-cemented acetabular shells.

The indications for use of the constrained liners compatible with this system are as follow: The devices are intended for general use in skeletally mature individuals undergoing primary and/or secondary revision surgery at high risk of hip dislocation due to a history of prior dislocation, joint or bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability and for whom all other options to constrained acetabular components have been considered.

Summary of Technologies: The devices to be covered by this 510(k) for are geometrically similar or identical to devices previously covered by 510(k).

Clinical and Non-Clinical Testing: None provided

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 4 - 2005

Ms. Patricia Sandborn Beres
Senior Regulatory Specialist
Biomet Manufacturing Corp.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K050124
Trade/Device Name: Porous Coated Acetabular Components
Regulation Number: 21 CFR 888.3330
Regulations: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
Regulatory Class: III
Product Codes: KWA, KWZ, LPH, MAY, MEH, and JDI
Dated: September 19, 2005
Received: September 20, 2005

Dear Ms. Beres:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

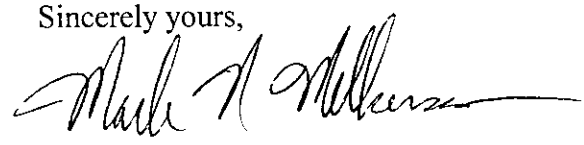
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050124

Device Name: Porous Coated Acetabular Components

Indications For Use: Cemented or non-cemented total hip replacement in cases of

1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
2) Rheumatoid arthritis
3) Correction of functional deformity
4) Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques.
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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use No (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K050124